

§ 516.30

21 CFR Ch. I (4–1–14 Edition)

decision to discontinue active pursuit of conditional approval or approval of such MUMS drug. FDA must terminate the designation upon such notification.

(b) A conditionally-approved or approved MUMS-designated drug sponsor must notify FDA at least 1 year before it intends to discontinue the manufacture of such MUMS drug. FDA must terminate designation upon such notification.

(c) MUMS designation shall terminate upon the expiration of any applicable period of exclusive marketing rights under this subpart.

(d) FDA may terminate designation if it independently determines that the sponsor is not actively pursuing conditional approval or approval with due diligence. At a minimum, due diligence must be demonstrated by:

(1) Submission of annual progress reports in a timely manner in accordance with § 516.30 that demonstrate that the sponsor is progressing in accordance with the drug development plan submitted to the agency under § 516.20 and

(2) Compliance with all applicable requirements of part 511 of this chapter.

(e) Designation of a conditionally approved or approved MUMS-designated drug and the associated exclusive marketing rights may be terminated if the sponsor is unable to provide sufficient quantities of the drug to meet the needs for which it is designated.

(f) FDA may also terminate MUMS-drug designation for any drug if the agency finds that:

(1) The request for designation contained an untrue statement of material fact; or

(2) The request for designation omitted material information required by this subpart; or

(3) FDA subsequently finds that the drug in fact had not been eligible for MUMS-drug designation at the time of submission of the request;

(4) The same drug, in the same dosage form, for the same intended use becomes conditionally approved or approved for another sponsor; or

(5) FDA withdraws the conditional approval or approval of the application for the new animal drug.

(g) For a conditionally approved or approved drug, termination of MUMS-drug designation also terminates the

sponsor's exclusive marketing rights for the drug but does not withdraw the conditional approval or approval of the drug's application.

(h) Where a drug has been MUMS-designated for a minor use in a major species, its designation will not be terminated on the grounds that the number of animals to which the drug could potentially be administered on an annual basis for the treatment, control, or prevention of the disease or condition for which the drug is being developed, including animals administered the drug as part of herd or flock treatment, subsequently increases.

(i) When a MUMS-drug designation is terminated, FDA will notify the sponsor in writing and will give public notice of the termination of the MUMS-drug designation.

§ 516.30 Annual reports for a MUMS-designated drug.

Within 14 months after the date on which a MUMS drug is granted designation and annually thereafter until approval, the sponsor of a MUMS-designated drug shall submit a brief progress report on the drug to the investigational new animal drug file addressed to the Director of the Office of Minor Use and Minor Species Animal Drug Development that includes the following information:

(a) A short account of the progress of drug development including a description of studies initiated, ongoing, and completed, and a short summary of the status or results of such studies;

(b) A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing; and

(c) A brief discussion of any changes that may affect the MUMS-designated drug status of the product. For example, situations in which testing data demonstrate that the proposed intended use is inappropriate due to unexpected issues of safety or effectiveness.

§ 516.31 Scope of MUMS-drug exclusive marketing rights.

(a) After conditional approval or approval of an application for a MUMS-designated drug in the dosage form and for the intended use for which MUMS-